ATTACHMENT B

REMARKS

By this amendment, Applicant has provided a revised set of claims 50-56 which reflect that the present invention is not disclosed or suggested in the newly cited prior art which actually teaches away from the present invention and does not relate to or suggest the combination of human serum albumin and a cleansing agent, in particular a soap. In particular, the Examiner has only cited references which relate to skin creams used for the primary purpose of an anti-wrinkle cream, or to theoretical papers assessing the thermodynamics of bovine serum albumin which clearly have nothing to do with the present invention wherein recombinant human serum albumin is used along with a soap cleansing agent. Accordingly, for reasons as set forth in detail below, Applicants submit that the present invention is not disclosed or suggested in the prior art, and that the present invention is thus patentable in its presently claimed form.

In the Official Action, the Examiner rejected Claims 39, 43 and 49 under 35 U.S.C. §102 on the basis of the Mausner reference, US 524331, as evidenced by the Palma 2002 article. The Examiner argued that the composition in Mausner was a composition comprising human serum albumin and further included glyceryl arachidonate which the Examiner argues acts as a "surfactant-cleansing agent." In addition, the Examiner argued that Mausner taught use of ascorbyl palmitate which "acts like surfactant (Palma et al. reference) as well wherein the surfactant, e.g., detergent, is well-known cleansing agent absent factual indicia to the contrary (*note that soap is a surfactant, see the attachment*)." See Official Action at Page 3 (emphasis in original).

In light of the fact that the present claims are directed to recombinant serum albumin, the rejection under Section 102(b) is now moot since the Examiner has conceded that Mausner does not disclose this subject matter. However, it is in fact that case that the Mausner reference does not disclose or suggest the present invention, and actually teaches away from it, because it does not disclose or suggest any cleansing agent, much less a soap, and the Examiner is clearly confused with regard to the terms such as "surfactant", "soap" and "detergent." In the first place the Mausner reference does not disclose or suggest any cleansing composition or ingredients whatsoever, much less soap, but instead is solely directed to a cream for combatting dryness and removing wrinkles. Indeed, the entire specification is devoid of any reference or suggestion to the composition being a cleansing composition, such as reflected in the background of the invention which reads as follows:

> This application is directed to an improved skin cream composition.
>
> Modern environmental conditions, such as heating and air conditioning, exposure to the sun, and environmental pollution exert severe stress on the skin and accelerate the natural aging process, resulting in wrinkles, loss of firmness and elasticity, dryness, and other cosmetically undesirable effects. Although a number of skin cream compositions already exist, there is a need for a simple to apply and effective all-in-one cosmetic treatment, such as a skin cream, that can counteract and minimize simultaneously the stress on the skin, improve firmness and elasticity, counteract dryness, so that wrinkles and other cosmetically undesirable effects appearing on the skin are prevented or delayed, as well as correcting existing wrinkles.

See Mausner patent, Col. 1. The Examiner's only argument that there is any cleansing agent or soap in the composition is based on two ingredients which clearly are not cleansing agents or soaps. With regard to glyceryl arachidonate, the

Examiner's own cited reference shows that this is **not** a cleansing agent, much less a soap. In particular, the Eppler et al. summary cited by the Examiner reads as follows:

> "Arachidonic acid (AS, has been used in cosmetics as a surfactant cleansing and emulsifying agent. Glyceryl arachidonate (GA), **a skin conditioning agent and emollient,** . . ."

See Eppler/MatTek Summary section, lines 1-3 (emphasis added) . In other words, while another compound is described as a cleansing agent, **glyceryl arachidonate is <u>not</u>.** This fact is supported in other articles showing this ingredient and others like it are used as "skin-conditioning agents, emollients and/or surfactants" (see attached Int. J. Toxicol. Abstract) and not as cleansing agents. Next, the Examiner apparently argues that Ascorbyl palmitate is a cleansing agent or a soap, when in fact the Palma article cited by the Examiner refers to it as a surfactant and is silent about any ability to act as a cleansing agent. Moreover, the Ascorbyl Palmitate is used in the Mausner composition in microscopic proportions, namely 0.01 to 0.03 **percent,** and once again no comments anywhere in Mausner would indicate that this agent is involved in any way as a cleansing agent.

This confusion on the Examiner in thinking that these ingredients are cleansing agents, and thus soaps, appears to be based on an assumption that a soap is a detergent and that all surfactants are soaps/ Such a concept is incorrect. As indicated in the attached definitions, a soap is merely one type of a surfactant, and is different than a detergent. The definition of surfactant is a "substance which prefers to exist at the boundary between two other substances", and in addition generally will act to reduce surface tension. While soap is a surfactant, it is only one type of surfactant and is different from other surfactants which are not soaps. Indeed, it is known that serum

albumin and other substances can reduce surface tension, but this does not make these substances into cleansing agents, much less a soap. The Examiner also seems to confuse "detergent" with "soap" as evident in the comment "wherein the surfactant, e.g., detergent, is well-known cleansing agent." To the contrary, a detergent is merely one type of surfactant, as reflected in the attached definitions. Indeed, surfactants are commonly used as emulsifiers, and this is reflected in the use of the glyceryl arachidonate and the ascorbyl palmitate in the Mausner patent. The Examiner is thus using "soap", "detergent" and "surfactant" interchangeably, and this is clearly incorrect.

Accordingly, the Mausner patent does not disclose or suggest the invention as presently claimed, and the rejection under Section 102(b) should be withdrawn.

In the Official Action, the Examiner rejected Claims 39, 41-43 and 47 under 35 U.S.C. §102 on the basis of the Nielsen article of June, 2000, in light of the Barczac article relating to the hazards of cosmetics and the definitions of "sodium laureth sulfate" as shown I the Paula-Begoun dictionary. As indicated above, this rejection is traversed in that Nielsen does not disclose or suggest a recombinant human serum albumin, and indeed does not relate whatsoever to a human serum albumin composition, but is a theoretical paper relating of surfactant binding to bovine serum albumin. Once again, Nielsen does not relate whatsoever to any cleansing agent, much less soap, but the Examiner appears to refer to sodium laurate in the Nielsen article, and combine this with the definitions of "sodium laureth sulfate" as a "detergent cleansing agent" In the first place, there is no reference anywhere in Neilsen to "sodium laureth sulfate", so there is no basis to make the connection as done by the Examiner.

To the contrary, the Nielsen article tests the effects of sodium dodecylsulfate (SDS) on bovine serum albumin, and the SDS and similar sulfates are described as surfactants. They are clearly not described or utilized as cleansing agents, much less the specific soap cleansing agent of the present claims. Moreover, since the Nielsen article is directed to bovine serum albumin, it would clearly have no relevance as a hypoallergenic composition, and since the Nielsen article has nothing to do with any composition designed for human treatment, it clearly does not disclose or suggest the hypoallergenic compositions of the present invention. Accordingly, this reference teaches away from any hypoallergenic composition such as the present one which uses recombinant human serum albumin, and thus cannot be combined with any additional reference to disclose or suggest the present claims. Accordingly, the rejection under Section 102(a) on the basis of Nielsen is respectfully traversed.

In the Official Action, the Examiner rejected Claims 39-40, 43 and 49 under 35 U.S.C. §103(a) as being unpatentable over Mausner when taken with the Miller EP patent application and Maki U.S. Pat. No. 5,759,802. This rejection, insofar as applied to the claims as amended, is respectfully traversed.

In the first place, as indicated above, the Mausner patent does not disclose or suggest any composition which includes a cleansing agent, much less the specific soap cleansing agent of the present claims, and instead relates to a skin cream used to combat dryness and remove wrinkles. Moreover, Mausner's composition specifically calls for the use of animal protein, and thus teaches away from the hypoallergenic compositions of the present invention. Finally, Mausner does not disclose or suggest

the use of a recombinant serum albumin, as reflected in the fact that this reference is not directed to any purely human serum albumin, much less a recombinant one.

Moreover, the deficiencies of the Mausner patent are not disclosed or suggested in any other prior art reference, and thus none of these other cited references can combine with Mausner to make obvious the present claims. For example, with regard to the Miller EP reference, this reference, like Mausner, is directed to an antiwrinkle preparation that includes human serum albumin, but this composition does not contain and in fact specifically excludes any such cleansing ingredients. In fact, in the Example given in Miller (at page 5), the user is instructed to cleanse the skin "such as by cleansing with soap or water. . .", thus confirming that the composition in Miller does not contain a cleansing agent and does not act as a cleansing composition. Finally, the Maki reference does not relate at all to the cleansing aspects of the present invention, and thus cannot be used to make the present claims obvious. Moreover, the Maki reference even discusses the problems associated with recombinant serum albumin which would have discouraged others from making any such composition using recombinant serum albumin. Although the Examiner indicates that anyone skilled in the art would be able or motivated to substitute recombinant albumin for natural albumin, the fact is that despite the knowledge of recombinant serum albumin, no one had disclosed or suggested using it in such compositions. Indeed the fact that the Mausner reference incorporates animal proteins and does not have any concern with the use of such proteins teaches away from the present invention wherein no such proteins are used, and the safer and more effective recombinant albumin is employed.

In short, no reference, either singly or in combination, discloses the hypoallergenic cleansing compositions of the present invention, and the Examiner's rejection on the basis of the Mausner, Miller and Maki references is respectfully traversed and should be withdrawn.

Finally, In the Official Action, the Examiner rejected Claims 39-40, 41-43 and 47-48 under 35 U.S.C. §103(a) as being unpatentable over Nielsen when taken with the Miller EP patent application and Maki U.S. Pat. No. 5,759,802. This rejection, insofar as applied to the claims as amended, is respectfully traversed.

In particular, as indicated above, Nielsen has nothing to do with the cleansing compounds of the present invention, but instead relates to theoretical studies of the effect of surfactants on albumin. Indeed, the specific surfactants cited in this study are non-soap surfactants which are clearly studied for their role in binding of bovine serum albumin, and not in any fashion with any cleansing ability. Indeed, the fact that Nielsen only relates to tests regarding BSA shows that this reference is totally unrelated to the present invention wherein a hypoallergenic recombinant human serum albumin composition is used as a cleansing composition including a soap. Accordingly, the Nielsen reference is totally distinct from the present invention, and in fact teaches away from the hypoallergenic composition of the invention because is uses BSA which would not be hypoallergenic as human serum albumin. Moreover, as indicated above, the other references cited by the Examiner do not disclose or suggest the missing elements of a cleansing agent that is a soap, nor the other aspects of the invention including the use of a hypoallergenic recombinant serum albumin in the composition.

Accordingly, the rejection on the basis of Nielsen, Miller and Maki is respectfully traversed and should be withdrawn.

In light of the amendments and arguments as set forth above, Applicants submit that the present application overcomes all prior rejections and has been placed in condition for allowance. Such action is earnestly solicited.

END OF REMARKS